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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/845,080	04/27/2001	Wendy Naimark	00-0238	1601

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EXAMINER	
NGUYEN, DAVE TRONG	
ART UNIT	PAPER NUMBER
1632	8

DATE MAILED: 10/24/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/845,080	Naimark et al.
Examiner	**Art Unit**
Dave Nguyen	1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Aug 16, 2002* .

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-36* is/are pending in the application.

4a) Of the above, claim(s) *4-6 and 18-36* is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *1-3 and 7-17* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 5
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

Applicant's election with traverse of Group I claims, claims 2-3 and linking claims 1, 7-17, and species of stainless steel in the response dated August 17, 2002 is acknowledged. Because applicant did not distinctly and specifically point out the supposed error in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 4-6, 18-36 have been withdrawn from further consideration by the Examiner, 37 C.F.R. 1.142(b), as being drawn to a non-elected invention.

Claims 1-3, 7-17, to which the following grounds of rejection are applicable, are pending.

Claims 1, 7-17 are objected because the claims embrace non-elected invention (Group III claims readable on the limitation of exposing the claimed suspension to a incompatible condition). The elected invention is the invention that only embraces a method of exposing a suspension comprising a pharmaceutically active agent and microparticles to a structural component that is compatible with said pharmaceutically active agent. Thus, the claims are required to be amended so as to reflect only on the elected invention.

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 2-3, 7-17, readable on a genus of microparticles, a genus of components, are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification contemplates a method of using any microparticle to increase a pharmaceutical effectiveness of any pharmaceutically agent exposed to any component that is incompatible to the agent, *e.g.,* a component that causes a reduction, for example, by at least 5% in pharmaceutical effectiveness upon contacting a pharmaceutical agent, pages 3 and 4 of the specification. With regard to the claimed genus of microparticles which must exhibit applicant's intended use, *e.g.,* to protect or increase a pharmaceutical effectiveness of any pharmaceutical agent upon contacting any incompatible component, the specification only teaches and discloses polymer microparticles on pages 6-7 of the specification. With regard to the claimed genus of components which are incompatible to any pharmaceutical agent, the specification only teach and discloses sufficiently of medical delivery devices composed of metals or certain polymers (poly ether ether ketones, polyimides, exposies, nylons, polycarbonates and glass, page 2 of the specification).

However, it is apparent that on the basis of applicant's disclosure, an adequate written description of the invention defined by the claims requires more than a mere statement that it is part of the invention and reference to potential methods and/or materials and/or components containing unspecified structures of molecules that are essential for the making the methods as broadly claimed; what is required is the knowledge in the prior art and/or a description as to the availability of a representative number of species of biochemical or molecular structures of "microparticles" and/or "components" which are employed in the context of delivery any pharmaceutical agent in which a pharmaceutical effectiveness of the agent must be increased upon contacting a generic incompatible component.

It is not sufficient to support the present claimed invention directed to micropartilces other than polymer microparticles and/or unspecified components which must exhibit the biological property of causing a reduction in pharmaceutical effectiveness upon contacting a pharmaceutically active matermal. A disclosure of no more than a polymeric microparticle in combination with a metal, certain polymers or a glass as in the instant case, is simply a wish to know the identity of any and/or all microparticles and/or components that are applicable to the claimed methods at the time the invention was made. The claimed invention as a whole is not adequately described if the claims require essential or critical elements which are not adequately

described in the specification and which is not conventional in the art as of applicants effective filing date. Claiming unspecified molecular structures of other microparticles and/or components that must possess the biological properties as contemplated by applicant's disclosure without defining what means will do so is not in compliance with the written description requirement. Rather, it is an attempt to preempt the future before it has arrived. (See *Fiers v. Revel*, 25 USPQ2d 1601 (CA FC 1993) and *Regents of the Univ. Calif. v. Eli Lilly & Co.*, 43 USPQ2d 1398 (CA FC, 1997)). Possession may be shown by actual reduction to practice, clear depiction of the invention in a detailed drawing, or by describing the invention with sufficient relevant identifying characteristics such that a person skilled in the art would recognize that the inventor had possession of the claimed invention. Pfaff v. Wells Electronics, Inc., 48 USPQ2d 1641, 1646 (1998). The skilled artisan cannot envision the detailed structure of a genus of the claimed microparticles and/or components for use within the context of the claimed invention, which must exhibit the contemplated biological functions, *e.g.,* an increase in a pharmaceutical effectiveness of any pharmaceutical active agent upon contacting any incompatible component, and therefore, conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the structures and/or methods disclosed in the as-filed specification. Thus, In view of the reasons set forth above, one skilled in the art at the time the invention was made would not have recognized that applicant was in possession of the claimed invention as presently claimed.

Claims 1-3, and 7-17 are rejected under 35 U.S.C. 112, first paragraph, because the specification is enabling only for claims limited to:

A method of using suitable polymer microparticles to protect a pharmaceutical effectiveness of a pharmaceutically active agent, comprising:

Providing a pharmaceutically acceptable suspension comprising a pharmaceutically active agent and suitable microparticles;

Exposing and contacting said pharmaceutically acceptable suspension to a medical delivery device which is incompatible with said pharmaceutically active agent, wherein said

polymer microparticles result in a pharmaceutical effectiveness of the pharmaceutically active agent in the absence of the microparticles.

The specification does not reasonably provide enablement for the presently pending claims encompassing any other combination of microparticles and component(s). The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized in In re Wands, 858 F.2d 731, 8USPQ2d 1400 (Fed. Cir. 1988). They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

Specifically, since the claimed invention is not supported by a sufficient written description (for possessing of the genus of the materials which are necessary for the practice of the claimed invention), particularly in view of the reasons set forth above, one skilled in the art would not known how to use and make the claimed invention so that it would operate as intended.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in—

(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or

(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

Claims 1-3, and 7-17, readable on:

A method of using suitable polymer microparticles to protect a pharmaceutical effectiveness of a pharmaceutically active agent, comprising:

Providing a pharmaceutically acceptable suspension comprising a pharmaceutically active agent and suitable microparticles;

Exposing and contacting said pharmaceutically acceptable suspension to a medical delivery metallic device which is incompatible with said pharmaceutically active agent, wherein said polymer microparticles result in a pharmaceutical effectiveness of the pharmaceutically active agent in the absence of the microparticles,

Are rejected under 35 USC 102(e) as being anticipated by Pinchuck *et al.* (US 2002/0107330).

Pinchuk *et al.* teach a medical device, *e.g.,* catheters, guide wires, stents, stent grafts, and a coating over at least a portion or the entirety of the medical device, the coating comprising a biocompatible block copolymer which further comprises polystyrene based polymers, *e.g.,* page 1, paragraphs 0010-0016, page 2, par. 0019-0022, column 2, p. 2, par. 0037, p. 3, par

0040. Suspension comprising the block copolymers and a therapeutic agent, wherein the microparticles are provided in an amount of an exemplified 1 wt% is disclosed on p. 4, par. 0059, page 8, pars 0176-0178, page 11, example 2. The dimensions of the polymeric coating of from about 0.5 microns to 50 microns are disclosed on page 9, par. 0195. Metallic based medical devices are disclosed on page 8, par. 0180. Adenoviral vectors as therapeutic agents are disclosed on page 5, paragraph 0089.

Absent evidence to the contrary and give all of the limitations are met by the disclosure of Pinchuck *et al.,* the claims are clearly anticipated by Pinchuck *et al.*

The following reference is also found relevant to the claimed invention.

Ragheb *et al.* (US 2002/0032414 A1, page 2, page 7, par. 0068), Shi *et al.* (US Pat No. 6,004,943) also teach a method of using suitable polymer microparticles to protect a pharmaceutical effectiveness of a pharmaceutically active agent, comprising:

Providing a pharmaceutically acceptable suspension comprising a pharmaceutically active agent and suitable microparticles;

Exposing and contacting said pharmaceutically acceptable suspension to a medical delivery device which is incompatible with said pharmaceutically active agent, wherein said polymer microparticles result in a pharmaceutical effectiveness of the pharmaceutically active agent in the absence of the microparticles,

No claim is allowed.

Any inquiry concerning this communication or earlier communications regarding the formalities should be directed to Patent Analyst Dianiece Jacobs, whose telephone number is **(703) 305-3388.**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner *Dave Nguyen* whose telephone number is **(703) 305-2024.**

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, *Deborah Reynolds*, may be reached at **(703) 305-4051.**

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is **(703) 305-7401**.

Any inquiry of a general nature or relating to the status of this application should be directed to the *Group receptionist* whose telephone number is **(703) 308-0196**.

Dave Trong Nguyen
Primary Examiner
Art Unit: 1632

DAVE T. NGUYEN
PRIMARY EXAMINER